Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Digital Health and Informatics | Meeting Summary

December 2nd, 2020 | 10:00am-1:00pm

Virtual Format (Zoom)

PURPOSE

To continue discussion of the digital health and informatics related topics in the context of the PDUFA reauthorization.

PARTICIPANTS

FDA		Industry	
Boris Brodsky	CDER	Rob Blanks	Ardelyx
Vid Desai	OIMT	Kristin Dolinski	PhRMA
Bushra Islam	CDER	Mathias Hukkelhoven	BMS
Chris Joneckis	CBER	Ryan Kaat	PhRMA
Khushboo Sharma	CDER	Robert Kowalski	Novartis
Mary Ann Slack	CDER	Heidi Marchand	Gilead
Ranjit Thomas	CDER	Camelia Thompson	BIO

At the eighth PDUFA VII Negotiation meeting, FDA and Industry reviewed a few additional modifications and questions regarding DHT draft language, with agreement to the overall substance of a draft commitment to refer to the steering committee.

FDA and Industry continued discussion on the Data/IT Modernization Proposal. FDA clarified that the goal of its Data and Technology Modernization Strategy is to promote consistency and improve interoperability. FDA and Industry clarified the distinction between one-time and recurring costs as well as the application of PDUFA to overall funding necessary for capabilities with broader use, such as for the Electronic Submissions Gateway. FDA noted that CBER IT Modernization resource request reflects CBER needs to accelerate IT modernization. The group recognized the value of international standards for interoperability, and the continued leadership and participation in initiatives with standards bodies and international consortia. FDA and Industry also discussed the value of implementing cloud technology pilot projects, and how to clarify several areas of potential ambiguity. The parties agreed to continue further clarification and refinement of a potential commitment in this area.

There were no other substantive proposals or significant controversies.